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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,663	03/14/2002	Nelson D. Horseman	AVI021	2987
26739	7590	06/01/2006	EXAMINER	
AVIGENICS, INC. 111 RIVERBEND ROAD ATHENS, GA 30605			QIAN, CELINE X	
			ART UNIT	PAPER NUMBER
			1636	
DATE MAILED: 06/01/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/099,663

Applicant(s)

HORSEMAN ET AL.

Examiner

Celine X. Qian Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 152-182 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 152-182 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Claims 152-182 are pending in the application.

This Office Action is responsive to the Amendment filed on 3/16/06.

#### ***Response to Amendment***

Claims 152-182 are rejected under 35 U.S.C. 112 1<sup>st</sup> paragraph for reasons discussed below.

Claims 156-163, 168 and 174-181 are rejected under 35 U.S.C. 112 2<sup>nd</sup> paragraph for reasons discussed below.

#### ***New Grounds of Rejection Necessitated by Amendment***

##### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 152-182 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 170-181 and 181 are drawn to an isolated nucleic acid comprising a nucleic acid having 90%-100% sequence identity with SEQ ID NO:1, and a nucleic acid sequence that hybridizes under stringent conditions to a nucleic acid sequence comprising SEQ ID NO:1. Claim 182 is drawn to an isolated nucleic acid comprising a gene expression controlling region

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comprises a nucleotide sequence that hybridizes under stringent condition to SEQ ID NO:1.

According to the specification, said nucleotide sequence would have at least 70% homology with SEQ ID NO:1 (see page 13, lines 28-30). As discussed in the previous office action, SEQ ID NO:1 is a 2.3 kb fragment 5' to chicken iFABP gene. The specification discloses that two fragments from the chicken iFABP gene (0.6 and 1.6 kb) direct expression of the reporter gene in a rat duodenum and a mouse gut epithelial cell lines, whereas one 1.1 kb fragment fails to show promoter activity in the reporter gene assay. The specification fails to teach whether the nucleic acid fragment represented by SEQ ID NO:1 have promoter activity. The specification also fails to teach whether nucleic acid molecules having sequence homology (70-99%) with SEQ ID NO:1 possess promoter/expression controlling activity. The specification also fails to disclose element(s)/structure(s)/sequence(s) the claimed fragments must have for said promoter or gene expression controlling function. As such, the structural and functional relationship between the claimed nucleic acid molecules and their promoter function is missing. Therefore, the written description requirement is not met.

Claims 152-169 introduces new limitation of "nucleotides 1115 to 1626 of SEQ ID O:1." Applicants assert that the support for this limitation can be found at page 38, 1<sup>st</sup> paragraph of Example 5, which discloses the cloning of 0.5 kb promoter that utilizes primer SEQ ID NO: 15 and 17. Applicants assert that aligning sequence of SEQ ID NO:1 with the primer would indicate that the 0.5 kb fragment is starting from 1115-1626. Applicants' argument is not persuasive because there is no specific teaching for this 0.5 fragment is 1115-1636 of SEQ ID NO:1. The legend of Figure 2 does not specifically indicate the nucleotide 1115-1626. A review of the Figure 2 itself does not reveal such information. While one can find out nucleotide 1115

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is the start of the PCR primer, nucleotide 1626 is somewhere in the middle of the reverse primer.

As such, there is no support for 1626. Therefore, this limitation constitutes new matter.

Claims 152-154, 156-169 recites nucleic acids that comprising a nucleic acid having 90%-100% sequence identity with 1115-1626 of SEQ ID NO:1, a nucleic acid sequence that hybridizes under stringent conditions to a nucleic acid sequence comprising 1115-1626 of SEQ ID NO:1 (said nucleotide sequence would have at least 70% homology with SEQ ID NO:1, see page 13, lines 28-30), an isolated eukaryotic cell comprising said nucleic acid, and method of producing a polypeptide using said eukaryotic cell. Although the specification discloses that two fragments from the chicken iFABP gene (0.6 and 1.6 kb) direct expression of the reporter gene in a rat duodenum and a mouse gut epithelial cell lines, it does not teach whether nucleic acid molecules having sequence homology (70-99%) with 1115-1626 of SEQ ID NO:1 possess promoter/expression controlling activity. The specification also fails to disclose element(s)/structure(s)/sequence(s) the claimed fragments must have for said promoter or gene expression controlling function. As such, the structural and functional relationship between the claimed nucleic acid molecules and their promoter function is missing. Therefore, the written description requirement is not met.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 156-163, 168 and 174-181 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Regarding claims 156-163, the claims recite “the isolated nucleic acid of claim 152 comprising a nucleotide sequence encoding a polypeptide or a polyadenylation signal, vector or origin of replication.” It is unclear whether the recited nucleotide sequence is part of the sequence recited in claim 152, sequence homologous to nucleotide 1115-1626 of SEQ ID NO:1, or in addition to the sequence recited in claim 152. It would be remedial to add “further” in front of “comprising” to overcome the instant rejection.

Claim 168 recites the limitation "nucleotide sequence encoding a polypeptide" in line 1-2. There is insufficient antecedent basis for this limitation in the claim. The parent claim 165 does not recite this limitation.

Regarding claims 174-181, the claims recite “the isolated nucleic acid of claim 170 comprising a nucleotide sequence encoding a polypeptide or a polyadenylation signal, vector or origin of replication.” It is unclear whether the recited nucleotide sequence is part of the sequence recited in claim 170, sequence homologous to SEQ ID NO:1, or in addition to the sequence recited in claim 170. It would be remedial to add “further” in front of “comprising” to overcome the instant rejection.

Claim 177 recites the limitation "the polyadenylation signal sequence" in line 1. There is insufficient antecedent basis for this limitation in the claim. The parent claim 170 does not have this limitation.

### ***Conclusion***

No claims are allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

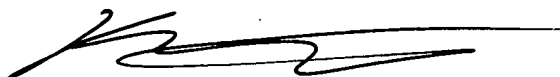
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Celine X Qian Ph.D.  
Examiner  
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CELINE QIAN, PH.D.  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to be 'C. Qian', written over a horizontal line.